



Food and Drug Administration
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April 30, 2015

Visioneering Technologies, Inc.
c/o Ms. Penny Northcutt, RAC, FRAPS, CQA
Regulatory Consultant and Official Correspondent
174 Watercolor Way Suite 103-403
Santa Rosa Beach, Florida 32459

Re: K150385

Trade/Device Name: Naturalvue (etafilcon A) Daily Disposable Soft (hydrophilic) Contact Lenses
NaturalVue (etafilcon A) SPHERE and ASPHERE
NaturalVue (etafilcon A) Toric
NaturalVue (etafilcon A) Multifocal
NaturalVue (etafilcon A) Multifocal Toric

Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: March 9, 2015
Received: March 10, 2015

Dear Ms. Northcutt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kesia Y. Alexander -A

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150385

Device Name

NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses

Indications for Use (Describe)

Spherical and Aspheric

NaturalVue (etafilcon A) Sphere and Asphere Daily Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of ametropia (myopia and hyperopia) in aphakic and/or non-aphakic persons with non-diseased eyes in powers from +20.00 to -20.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

Toric

NaturalVue (etafilcon A) Toric Daily Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 diopters.

Multifocal Spherical

NaturalVue (etafilcon A) Multifocal Daily Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic and/or nonaphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and with non-diseased eyes who may require a reading addition of up to +3.00D. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

Multifocal Toric

NaturalVue (etafilcon A) Toric Multifocal Daily Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic and/or non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and with non-diseased eyes who may require a reading addition of up to +3.00D. The lenses may be worn by persons who exhibit astigmatism of 10.00 diopters or less.

NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

The lenses are intended for single-use disposable wear.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510k Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

DATE	February 13, 2015
APPLICANT	Visioneering Technologies, Inc. Stephen Snowdy, CEO 4555 Mansell Road Suite 300 Alpharetta, GA 30022 770-521-4358 (office phone) 404-863-8892 (cell phone) ssnowdy@vtivision.com (email)
OFFICIAL CORRESPONDENT	Penny Northcutt, RAC, FRAPS, CQA 174 Watercolor Way, Suite 103-403 Santa Rosa Beach, FL 32459 678-428-6978 (phone) 866-630-4082 (fax) pennynorthcutt@theregsolutions.com (email)
TRADE NAME	NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses
COMMON NAME	Soft (hydrophilic) Contact Lenses (daily wear) Soft (hydrophilic) Contact Lenses (disposable)
DEVICE CLASSIFICATION AND PRODUCT CODE	Class II Lenses, Soft Contact, Daily Wear, per 21 CFR 886.5925, Product Code: LPL Class II Lens, Contact, (Disposable), per 21 CFR 886.5925, Product Code: MVN
PREDICATE DEVICE	K140025 Pegavision Corporation, NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses

SUBSTANTIAL EQUIVALENCE:

It is Visioneering Technologies, Inc.'s conviction that the data submitted in this 510(k) provides evidence of substantial equivalence for the NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses with the same established safety profile and effectiveness of the predicate device K140025 NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses.

DESCRIPTION OF THE DEVICE:

The NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses are visibility-tinted, containing a UV blocker and are available in a spherical, aspheric, toric, multifocal, and multifocal toric designs. They are manufactured by cast molding method. The device is an ionic hydrogel lens derived from etafilcon A which is a co-polymer of 2-Hydroxyethylmethacrylate (2-HEMA) and Methacrylic Acid (MAA), cross-linked with ethylene glycol dimethacrylate (EGDMA) and 1,1,1-trimethylolpropane trimethacrylate (TMPTMA) via photo-polymerization. The copolymer consists of 42% etafilcon A and 58% water by weight when immersed in normal buffered saline solution. The lenses are tinted blue using C.I. Reactive Blue 19 to make them more visible for handling. The lenses contain a UV blocker, a benzotriazole UV absorbing monomer to block UV radiation. The average transmittance characteristics of the lenses are less than 5% in the UVB range of 280-315nm and less than 30% in the UVA range of 316-380nm. Lenses are supplied sterile in sealed blister package containing sterile isotonic borate buffered saline solution.

INTENDED USE/INDICATIONS FOR USE:**NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses****Spherical and Aspheric**

NaturalVue (etafilcon A) Sphere and Asphere Daily Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of ametropia (myopia and hyperopia) in aphakic and/or non-aphakic persons with non-diseased eyes in powers from +20.00 to -20.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

Toric

NaturalVue (etafilcon A) Toric Daily Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 diopters.

Multifocal

NaturalVue (etafilcon A) Multifocal Daily Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic and/or non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and with non-diseased eyes who may require a reading addition of up to +3.00D. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

Multifocal Toric

NaturalVue (etafilcon A) Toric Multifocal Daily Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic and/or non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and with non-diseased eyes who may require a reading addition of up to +3.00D. The lenses may be worn by persons who exhibit astigmatism of 10.00 diopters or less.

NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

The lenses are intended for single-use disposable wear.

TECNOLOGICAL CHARACTERISTICS:

Historical Clinical Use

etafilcon A lenses have been used widely. Their safety and effectiveness have been well established and documented. Their safety and effectiveness can be further exemplified by the following lenses, as well as many others as discussed in the 510(k), cleared by FDA:

- ACUVUE (etafilcon A) Contact lens, clear and visibility tint with UV blocker, K962804 submitted by Vistakon USA
- ACUVUE (etafilcon A) contact lens, clear and visibility tint with UV blocker, K991134 submitted by Vistakon USA
- Aquamax (etafilcon A) Disposable Soft (Hydrophilic) Contact Lenses, K120028 submitted by Pegavision Corporation, Taiwan
- NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses, K140025 submitted by Pegavision Corporation, Taiwan

NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses from the previous FDA cleared K140025 did not require clinical studies as the USAN name and manufacturing processes are the same as the above-mentioned predicate (and reference) devices.

Non-Clinical Study

All tests were conducted in accordance with the May 1994 FDA Guidance Document for Daily Wear Contact Lenses.

The non-clinical performance tests have been performed to demonstrate the safety and effectiveness of NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses and establish substantial equivalence to the predicate NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses (K140025). The evidence of substantial equivalence to the predicate lenses is described below.

a) Material Properties Testing

The material properties of NaturalVue (etafilcon A) Soft (Hydrophilic) Contact Lenses were tested as illustrated in the following table.

	Proposed Device	K140025 Predicate
Production Method	Cast-Molded	Cast-Molded
USAN Name	etafilcon A	etafilcon A
Material Classification	Group 4 high water ionic	Group 4 high water ionic
Water Content (%)	58%	58%
Refractive Index	1.4023	1.4023
Oxygen Permeability (edge corrected) @ 35°C	19.3 x 10 ⁻¹¹ (cm ² /sec)(ml O ₂ /ml-mmHg)	19.3 x 10 ⁻¹¹ (cm ² /sec)(ml O ₂ /ml-mmHg)
Percent Transmittance		
% T at 593nm	> 95%	> 95%
% T at 380-315nm	< 30%	< 30%
% T at 315-280nm	< 5%	< 5%

b) Biocompatibility

The standard cytotoxicity, maximization sensitization, and ocular irritation tests were carried out for the predicate K140025 NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses, and therefore apply to NaturalVue (etafilcon A) Daily Disposable Soft

(Hydrophilic) Contact Lenses. Negative responses were recorded for all tests. The validity of blister packaging for these lenses was demonstrated by passing the standard extraction tests.

c) Microbiology

The steam sterilization process has been validated to deliver a minimum SAL of 10^{-6} , thereby complying with the requirement of FDA Group 4. There is shelf-life stability supporting that these lenses remain sterile through the expiration date claimed for the product.

d) Bacteriostatic Validation

The steam sterilizer was tested for effectiveness by measuring and demonstrating the uniformity of temperature at different locations inside the sterilizer over test period. Tested microorganisms were killed under tested conditions as compared to control.

Lenses remained sterilized and there was no microbial growth for a period of 4 years tested under accelerated conditions. Seal of lens packages remained tight for a period of 4 years as demonstrated by the constant peeling strength tested under accelerated conditions.

e) Leachability

Studies were conducted to determine the leachable materials from the finished lenses. The results show that, at the levels of the detection reported, there are no leachable monomers and additive residues.

CONCLUSION:

Based on the performance and manufacturing verification studies, it can be concluded that the NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses are equivalent to the predicate device K140025 NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses with respect to intended use, principles of operation, and technological characteristics.